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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,459	07/16/2001	Gilles Guichard	99 BB CNR URE	9090
466	7590	11/23/2004	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			KIFLE, BRUCK	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,459

Applicant(s)

GUICHARD ET AL.

Examiner

Bruck Kifle, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004 and 01 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/04/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's amendments and remarks filed 08/04/04 and 09/01/04 have been received and reviewed. Claims 54-72 are now pending in this application.

Information Disclosure Statement

The information disclosure statement filed 08/04/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. A line has been drawn through the citations that Applicants have not submitted.

Improper Markush Rejection

Claims 54-72 are rejected under a judicially created doctrine as being drawn to an improper Markush group, that is, the claims lack unity of invention. The basis of this rejection is the same as given in the previous office actions and is incorporated herein fully by reference. The claims still lack "a community of chemical or physical characteristics" which justify their inclusion in a common group, which inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The instant claims do NOT have a significant structural feature. The only fragment that is common is NH-C(O). This, however, is not a significant feature. This common structural feature of formula I, is **not** a patentable advance over the prior art.

The special technical feature is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. The feature is, thus, not special if it is known.

Claim Rejections - 35 USC § 112

Claims 54-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) The group “GP” is defined as “a protective group selected from an oxycarbonyl (ROCO), acyl, alkyl, aryl, a group of formula -CONHR, a phthalimido group (with $R^1 = 0$), a biotinyle group (structure is given) and O_2 (with $R^1 = 0$). This is unclear. An alkyl group or aryl group are not protective groups. Similarly CONHR is not a protective group. The O_2 is an oxygen molecule and not understood in the context of the definition of GP.

ii) In the definitions of R^1 and R^i , the intended substituents are not known. The nature of the cycle formed by R^1 and R^i is unclear.

iii) The metes and bonds of “X” is unclear. X is defined in claim 52 as “a group conferring on the compound of formula (I bis) a structure of an activated derivative of carbamic acid, wherein said X group is derived from a compound selected from phenols, optionally substituted with at least one nitro or at least one halogen, or from hydroxylamine compounds, imidazole and tetrazole.” It is defined as being derived from other compounds in claims 57, 58 and 60. One skilled in the art cannot say what a derived group looks like.

iv) Claims 60, 64, 65-67 lack antecedent basis in claim 52. X is not permitted to be a N-hydroxysuccinimide group in claim 52. The search and examination of the claims is limited to compounds of formula (I bis) wherein X represents -O-succinimidyl.

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Claims 64-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The closest prior art compounds are taught by Guichard et al. (*J. Org. Chem.* **1999**, *64*, 8702-8705). The reference teaches structurally similar compounds that differ from the compounds in these claims by the nature of the protecting group. Thus, these claims have Fmoc as a protecting group over the t-BuOCO of the prior art compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK

November 19, 2004